K03 1928

OCT 24 2003

510(k) Summary

Summary of Safety and Effectiveness

Company information

Braun GmbH
Frankfurter Strasse 145
D-61476 Kronberg
Germany

Device Identification

Trade Name – Braun Thermoscan® IRT 4000 series
– Braun Thermoscan® PRO 4000 series
Classification Name – Thermometer, Clinical, Electronic
Classification – Class II
Product Code – 80 FLL

Predicate Devices

Braun Thermoscan IRT 3000 infrared ear thermometer (consumer)
Braun Thermoscan PRO 3000 infrared ear thermometer (professional)

Device Description

Braun Thermoscan infrared ear thermometers are hand-held, battery-powered devices that are intended to be used for the intermittent measurement and monitoring of human body temperature of people of all ages. They measure infrared energy that is emitted from the tympanic membrane and surrounding tissue.

Intended Use and Indications for Use

Intermittent measurement and monitoring of human body temperature on people of all ages.

- IRT 4000 series – consumers in a home use environment.
- PRO 4000 series – professionals in a professional environment.

Comparison of the Braun ThermoScan IRT/PRO 4000 and the Braun Thermoscan IRT/PRO 3000 infrared ear thermometers

The basic design of the Braun ThermoScan IRT/PRO 4000 and the Braun Thermoscan IRT/PRO 3000 are similar. The fundamental scientific technology of the new devices has not changed from that of the predicate devices. The materials used to fabricate the thermometer case, speculum, buttons and Lens Filters/Probe Covers are the same as the IRT/PRO 3000 series thermometers.

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The following are the primary differences between the IRT/PRO 4000 and the IRT/PRO 3000 series thermometers.

1. The IRT/PRO 4000 series thermometer family incorporates a new probe design that contributes to increased repeatability of temperature measurements. The infrared sensor has been repositioned from the base of the IR wave-guide closer to the interior tip of the probe.

2. Integrated into the IR sensor are the ambient sensor and a heating element. The heating element warms the probe tip close to the most likely temperature within the range of the intended target temperatures, (i.e., human body temperature 37°C) and results in a reduction of the blackbody effect and increased repeatability of successive temperature measurements.

3. A positive feedback system (ExacTherm®) informs the user that the proper conditions and placement have been established to obtain an accurate temperature measurement. The user is signaled when the probe has been properly positioned in the ear canal and the conditions are correct for a complete measuring process. If the correct position is not obtained, a position error will be displayed.

Compliance with Consensus Standards

The Braun Thermoscan IRT/PRO 4000 series conform to Consensus Standards and other Standards that include:

ASTM E1965–98 – Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

IEC 60601-1:1988 Cor 1 1995 – Medical Electrical Equipment – Part 1 General requirements for Safety

IEC 60601-1:1988 – Medical Electrical Equipment – Part 1 General requirements for Safety, 1998; Amendment 1, 1991-11, Amendment 2, 1995-03

IEC 60601-1-4:2000 – Medical Electrical Equipment – Part 1-4 General requirements for Safety – Collateral Standard: Programmable Electrical Medical Electrical Systems

IEC 60601-1-2:2001 – Medical Electrical Equipment – Part 1 General requirements for Safety; Electromagnetic Compatibility – Requirements and Tests

AAMI/ISO 14971:2000 – Medical Devices – Application of Risk Management to Medical Devices

AAMI/ISO 14971-1:2000 – Medical Devices – Risk Management – Part 1: Application of Risk Analysis

EN 540:1993 – Clinical Investigation of Medical Devices for Human Subjects

EN 980:1997+ A1:1999 – Graphical Symbols for Use in the Labeling of Medical Devices

ISO 15223:2000 – Symbols Used with Medical Device Labels, Labeling, and Information to be Supplied

Clinical Results

A comparison study and clinical repeatability testing was performed on the following four age groups; 0-3 years, 4-10 years, 11-65 years, and >65 years. This clinical comparison study demonstrated that the Braun ThermoScan IRT 4000 measures ear canal temperature as well as the previously approved model IRT 3000 in all age groups. The ear temperatures obtained with the IRT 4000 were highly related to temperatures measured at the oral and axillary sites. Differences were within clinical acceptability. The clinical repeatability of the device is statistically and clinically acceptable.

Consumer vs. Healthcare Professional Comparability Study Results

The difference in measurements obtained by health care professionals and consumers with the Braun ThermoScan® IRT/PRO 4000 ear thermometer was tested. Consumers' measurements obtained were comparable to the professional measurements, collectively, for pooled professionals, and each individual category of professionals.

The repeatability of temperatures obtained from the consumers was comparable to the repeatability of the temperatures obtained from the professionals.

Conclusion

The Braun Thermoscan IRT/PRO 4000 series thermometers:

- conform to Consensus Standards that are applicable to infrared ear thermometers,
- are technically and functionally substantiality equivalent to the predicate devices, and
- function similarly in the hands of consumers and healthcare professionals.

Therefore the IRT/PRO 4000 series thermometers do not raise any significant questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2003

Braun GmbH
C/O Mr. Fred Schlador
Regulatory Resources, LLC
6183 Paseo Del Norte, Suite 150
Carlsbad, California 92009

Re: K031928
Trade/Device Name: Braun Thermoscan PRO 4000 Series (Professional Use Environment) and Braun Thermoscan IRT4000 Series (Home Use Environment)
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 5, 2003
Received: September 8, 2003

Dear Mr. Schlador:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

[redacted]

Indications for Use Statement

510(k) Number: K031928

Device Name: Braun ThermoScan® PRO 4000 series and IRT 4000 series Infrared ear thermometer

Indications for Use:

PRO 4000 series

The Braun Thermoscan PRO 4000 series infrared ear thermometers are indicated for the intermittent measurement and monitoring of human body temperature by professionals in a professional use environment.

IRT 4000 series

The Braun Thermoscan IRT 4000 series infrared ear thermometers are indicated for the intermittent measurement and monitoring of human body temperature by consumers in a home use environment.

Patricia Cucuzza

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K031928

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use_____ OR Over the Counter ✓
(Per 21 CFR 801.109